Supporting Statement A
Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j))
CMS-10305, OMB 0938-1115

Background

The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations [MAOs], Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR 422.516(a) and 423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data (depending on the type of contracts they have in place with CMS).

In order for the reported data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations (SOs). To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation process. SOs are responsible for hiring external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials, which CMS outlines in the "Standards for Selecting Data Validation Contractors" document. For the retrospective review in 2022, the DVCs will review data submitted by SOs for contract year (CY) 2021.

CMS developed standards and data validation criteria for specific Medicare Part C and Part D reporting requirements that the DVCs use in validating the SOs' data. The standards are listed in Appendix J. The data validation standards for each reporting section include standard instructions relevant to the type of information that should be reviewed, and the reporting section-specific criteria (RSC) that are aligned with the Medicare Part C and Part D Reporting Requirements. The standards and criteria describe how the DVCs should validate the SOs' compilations of reported data, taking into account appropriate data exclusions, and verifying calculations, source code, and algorithms. The data validation reviews are conducted at the contract level given that the Medicare Part C and Part D data are generally available at the contract level, and the contract is the basis of any legal and accountability issues concerning the rendering of services.

The review is conducted over a three-month period (April – June) following the final submission of data by the SOs. The DVCs employ a set of information guides and collection tools when performing their reviews. The Organizational Assessment Instrument (Appendix B) is completed by the SO prior to the review and is shared with the DVCs. The tool used to record the results of the data validation is the "Findings Data Collection Form" (FDCF). The FDCF, displayed in Appendix J, allows contractors to record notes, reference data sources, and capture findings for the different standards and criteria specified for a given reporting section. The DVC submits the completed FDCF to CMS via the Health Plan Management System (HPMS).

The main changes for the 2022 DV documents were relevant to the type of information that should be reviewed, and the RSC to ensure alignment with the approved Medicare Part C and Part D reporting requirements. A detailed crosswalk of those changes is provided.

CMS uses validated, plan-reported data to calculate two Star Ratings measures (Medication Therapy Management Programs (Part D)), and Special Needs Plans Care Management (Part C)) and one Display measure (Grievances (Part C and D)). For more information please see the Star Ratings and Display technical notes posted here https://www.cms.gov/Medicare/PrescriptionDrug-Coverage/PrescriptionDrugCovGenIn/PerformanceData. Star Ratings are used to calculate Quality Bonus Payments, which are discussed in more detail in the Advance Notices and Rate Announcements published at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.

Justification

1. Need and Legal Basis

Sections 1857(e) and 1860D-12 of the Social Security Act ("the Act") authorize CMS to establish information collection requirements with respect to MAOs and Part D sponsors. Section 1857(e) (1) of the Act requires MAOs to provide the Secretary of the Department of Health and Human Services (DHHS) with such information as the Secretary may find necessary and appropriate. Section 1857(e) (1) of the Act applies to Prescription Drug Plans (PDPs) as indicated in section 1860D-12. Pursuant to statutory authority, CMS codified these information collection requirements in regulation at §§422.516(g) *Validation of Part C Reporting Requirements,* and 423.514(j) *Validation of Part D Reporting Requirements* respectively.

Consistent with the regulatory authority to collect information, CMS developed specific Medicare Part C and Part D reporting requirements to assist in monitoring the Medicare Part C and D programs, to respond to questions from Congress, oversight agencies, and the public. These inquiries cover a variety of topics, including costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and Part D Plans. The current Medicare Part C reporting requirements (OMB 0938-1054) may be accessed at: http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements.html. The current Medicare Part D reporting requirements (OMB 0938-0992) may be accessed at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html.

2. Information Users

Data collected via Medicare Part C and Part D reporting requirements are an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of

Medicare benefits to beneficiaries. CMS uses the findings collected through the data validation process to substantiate the data reported via Medicare Part C and Part D reporting requirements. Data validation provides CMS with assurance that plan-reported data are credible and consistently collected and reported by Part C and D SOs. CMS uses validated data to respond to inquiries from Congress, oversight agencies, and the public about Part C and D SOs. The validated data also allows CMS to effectively monitor and compare the performance of SOs over time. Validated plan-reported data may be used for Star Ratings, Display measures and other performance measures. Additionally, SOs can take advantage of the DV process to effectively assess their own performance and make improvements to their internal operations and reporting processes.

3. Use of Information Technology

SOs use HPMS when submitting data to CMS. DVCs also use HPMS for submitting or entering findings from the FDCF; specifically, DVCs use the Plan Reporting Data Validation Module (PRDVM), which mirrors the FDCF. CMS grants access to HPMS to each user. System access requires an individual login and password but does not require an electronic signature.

4. Duplication of Efforts

The data validation process does not result in a duplication of similar information.

5. Small Businesses

The data validation process does not impose a significant impact on small businesses and other entities.

6. Less Frequent Collection

The data are collected and validated annually. If the collection is not conducted or is conducted less frequently, the reliability, validity, completeness, and comparability of the Medicare Part C and Part D reporting requirements data cannot be ensured. CMS could not confidently use the data for public reporting and the value of the data for monitoring would be questionable. In addition, CMS makes available data from some reporting sections in the form of public use files (PUFs) in support of its transparency goals. It, therefore, is especially important that the data be valid and reliable.

7. Special Circumstances

Respondents are required to retain records (excluding health, medical, government contract, grant-in-aid, or tax records) for more than three years. §§42 CFR 422.504(d) and 423.505(d), MAOs and

Part D sponsors must agree to maintain books, records, documents, and other evidence of accounting procedures and practices for 10 years.

Otherwise, there are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on June 17, 2021 (86 FR 32269). Eight public comments were received. They are attached to this package along with our responses.

- CM has requested the DV documents be posted in the Federal Register on October 14, 2021 (86 FR 57151) and the 30-day comment period will end November 13, 2021.
- From November 15, 2021 to December 15, 2021, CM staff will review all received comments and questions, and revise the documents appropriately. In addition, CM staff will prepare a document summarizing responses to comments and questions. Final DV documents will be delivered for OMB review by December 31, 2021.

9. Payments/Gifts to Respondents

There are no gifts to the respondents. However, as a matter of compliance with the requirements of this information collection request (ICR) and the Medicare program, sponsors will achieve Star Ratings and Display measure rates based on the data that undergo data validation. Sponsors are incentivized to do well in the Star ratings. Sponsors that fail to comply with the requirements

contained in this ICR, that is, they fail to have their data validated, will receive compliance actions.

10. Confidentiality

CMS adheres to all confidentiality-related statutes, regulations, and agency policies.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

Burden for this iteration of the CMS Medicare Part C and Part D data validation program are described below. A discussion of the revisions to our currently approved estimates are set out in section 15 of this Supporting Statement.

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. Applying BLS' data to the DVCs, we expect respondents would be a Management Analyst.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Analysts	13-1111	$45.94	45.94	91.88

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

We have based these burden estimates with the consideration that data validation is conducted for each Part C/D contract, and that the contract is the basis for any legal or accountability issues. Change in the level of effort is quantified by the net changes in the number of lines of instruction in the FDCF, as it is the instrument completed by the DVC. We calculated the projected cost of the 2022 burden using the wage estimates described above, and updated the number of burden hours using the number of lines of instruction in the 2022 FDCF as outlined in Table 3 below. We also updated the number of contracts validated during the most recent DV cycle.

The estimates below are an individual contract's burden for data validation. The decreased burden is due to the cumulative elimination of 260 lines of instruction from the Part C and Part D Grievances section for 2022 data validation for C&D reporting. In addition, we decreased burden in the Part D Medication Therapy Management (MTM) section by eliminating 111 lines of instruction for 2022 data validation for Part D reporting.

Table 2: OMB Approved Cost Burdens, Data Validation Review CY 2020 DV Cycle

	MA only	**PDP**	**MA-**
2019 PRA LOE (Hours) per contract	12.85	18.48	29.30
Number of Reporting items in the FDCF	499	523	1022
Time per FDCF item *(Calculated by Total hours per contract / # reporting items in FDCF)*	.26	.035	.029

Table 3: Estimated Cost Burden at Individual Contract Level, Data Validation Review CY 2022 DV Cycle

Assumption/Estimate	**MA only**	**PDP only**	**MA-PD**	**All contracts**
Hourly Wage: Analyst	$45.94	$45.94	$91.88	
Number of contracts *(# contracts completing 2018*	14	43	704	
Number of Reporting items in FDCF for 2020 DV cycle	460	469	929	

Total hours (per contract) *(2018 Time per FDCF item * 2020# reporting items in*	11.85	16.57	28.51	
Total Burden Hours (All contracts) *(Total hours per contract * # contracts)*	*165.86*	*721.37*	*20,067.56*	**20,945.80**
Total Burden Cost *(All contracts) *Wage)*	*$15,239.41*	*$65,452.91*	*$1,843,807.53*	**$1,924,499.85**

Information Collection Instruments/Instruction/Guidance Documents

Data Validation Procedure Manual
Appendix B: Data Validation Standards
Appendix E: Organizational Assessment Instrument
Appendix J: Findings Data Collection Form (FDCF)

13. Capital Costs

There is no capital cost associated with the data validation activities.

14. Cost to Federal Government

It will cost an estimated $300,000 to maintain the Health Plan Management System (HPMS).

15. Program and Burden Changes

Table 4 lists the three Part C and four Part D reporting sections that will undergo validation for a total of seven sections validated.

Table 4: Part C and Part D Reporting Sections in the 2022 Data Validation Cycle	
Part C Reporting sections	**Part D Reporting Sections**

• Part C Grievances • Organization Determinations and Reconsiderations • Special Needs Plans Care Management	• Medication Therapy Management (MTM) Programs • Part D Grievances • Coverage Determinations and Redeterminations • Improving Drug Utilization Review Controls

Table 5 summarizes changes in calculation factors between the 2020 ICR and the 2022 ICR for the data validation of Part C and Part D reporting requirements.

Table 5: 2020 vs. 2022 Changes in Calculation Factors

Factor	ICR 2020 Annual Estimate	ICR 2022 Annual Estimate
Total Number of CMS Contracts (MA-only, PDP and MA-PDs)	553	761
Number of Reporting Sections Undergoing Data Validation	3 (Part C) 4 (Part D) 7 (Total sections)	3 (Part C) 4 (Part D) 7 (Total sections)
Total Industry Level of Effort (Across all contracts)	15,332	20,945.80
Total Industry Cost (Across all contracts)	$1,391,534	$1,924,599.85

https://hpms.cms.gov/app/NAU/NewsSearch.aspx

16. Publication/Tabulation Dates

Collection of the relevant Medicare Part C and Part D data occurs during a three-month period each year from April 1 through June 30.

17. Expiration Date

The expiration date will be displayed within the DV documents (Appendices B and E and the DV manual).

18. Certification Statement

There are no exceptions to the certification statement.